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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,243	07/14/2003	Earle Keirstead	8567-594U1	5833
570	7590	01/12/2005	EXAMINER	
AKIN GUMP STRAUSS HAUER & FELD L.L.P. ONE COMMERCE SQUARE 2005 MARKET STREET, SUITE 2200 PHILADELPHIA, PA 19103-7013			SMALLEY, JAMES N	
			ART UNIT	PAPER NUMBER
			3727	

DATE MAILED: 01/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/619,243	KEIRSTEAD ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	James N Smalley	3727	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 1-11 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 12 and 13 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 14 July 2003 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All
  - b) Some \*
  - c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)              |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/16/03</u> . | 6) <input type="checkbox"/> Other: _____.  |

**DETAILED ACTION*****Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-11, drawn to method and apparatus, classified in class 264, subclass 328.1.
  - II. Claims 12 and 13, drawn to a product, classified in class 215, subclass 200.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as (apparatus and method) and product made. The inventions in this relationship are distinct if either or both of the following can be shown: (1) that the apparatus and method as claimed are not an obvious apparatus or method for making the product and the apparatus and method can be used for making a different product or (2) that the product as claimed can be made by another and materially different apparatus and method (MPEP § 806.05(g)). In this case the product as claimed can be made by another and materially different apparatus and method such as an apparatus without a valve within the core or gate used during injection.

2. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
3. Because these inventions are distinct for the reasons given above and the search required for Group II is not required for Group I, restriction for examination purposes as indicated is proper.
4. During a telephone conversation with Mr. Martin Belisario on Dec. 21, 2004 a provisional election was made with traverse to prosecute the invention of Group II, claims 12 and 13. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-11 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is

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no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Drawings***

5. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the top surface being substantially flat, as disclosed in claim 12, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Examiner notes the figures 1 and 5a-e show the cap in cross section. It is noted the top surface does not appear to be substantially flat. Fig. 3 does not conclusively show the top surface as substantially flat.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Connor et al. US 4,471,879.

Connor '879 teaches a pharmaceutical cap (28) comprising a substantially flat top side (unlabeled, but best seen in fig. 6), bottom side, side skirt (unlabeled), small cylindrical ring (34) extending downwardly from the center of the bottom side, and gate mark (unlabeled, but best seen in figs. 7-8, disposed at the center point of the bottom surface).

#### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Connor et al. US 4,471,879 in view of Akao US 5,225,259.

To the degree that Connor '879 does not anticipate a gate mark, Akao '259 teaches a plastic cap embodiment in fig. 1, having a gate mark (5) molded from the bottom surface. Although the patent is silent as to the benefit of this embodiment, the reference does teach the benefit of using an indent (3) in the embodiments of figs. 3 and 4. Col. 4, lines 13-16 teach, "This structure is preferable in points of appearance and molding. Since the gate mark (5) does not project out, its after-treatment is not necessary. Stringiness trouble also decreases."

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the cap of Connor '879, providing a gate mark on the bottom surface, motivated by the benefit of eliminating after-treatment, and improving cap molding and appearance.

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10. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Connor et al. US 4,471,879 in view of Shimada JP 01016017.

To the degree that Connor '879 does not anticipate a gate mark, Shimada '017 teaches it is known to form the gate mark (20b) of thermoplastic caps. In the Advantage section of the English abstract, we are taught the advantage of the molding process is highly precise molding, and improved appearance.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the gate mark on the bottom surface of the cap of Connor '879, as taught by Shimada '017, motivated by the benefit of improved appearance.

#### ***Conclusion***

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

US 4,111,322

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James N Smalley whose telephone number is (571) 272-4547. The examiner can normally be reached on M-Th 9-6:30, Alternate Fri 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lee Young can be reached on (571) 272-4549. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

jns



Stephen K. Cronin  
Primary Examiner